

Investigative Report
Title VI Administrative Complaint File No. 5R-04-R5
Appendix A
Supplemental Findings of Fact

1. By letter dated January 31, 2004, The Reverend [REDACTED] requested that IDEM deny the Midwest Medical Permit Application. (VFC Document 30028627, Letter from the Reverend [REDACTED] to John Hale, Office of Land Quality, IDEM, dated January 31, 2004) Reverend [REDACTED] was not on the mailing list utilized by IDEM for distribution of the Notice of Decision.
2. By letter dated February 5, 2004, [REDACTED] indicated to IDEM her opposition to the Midwest Medical Permit Application. (VFC Document 30028624, Letter from [REDACTED] to John Hale, Office of Land Quality, IDEM, dated February 5, 2004) Ms. Darling was on the mailing list utilized by IDEM for distribution of the Notice of Decision.
3. By letter dated February 10, 2004, [REDACTED] requested that the Midwest Medical Permit Application be rejected on the basis of existing contamination in the area, the fact that there were several schools and day care centers in close proximity to the proposed facility, and the allegations, as described in an enclosed newspaper article, that Midwest Medical did not comply with required environmental and safety regulations. (VFC Document 30028391, Letter from [REDACTED] to John Hale, Office of Land Quality, IDEM, dated February 10, 2004) [REDACTED] was on the mailing list utilized by IDEM for distribution of the Notice of Decision.
4. By letter dated February 12, 2004, [REDACTED] and [REDACTED] requested that the Midwest Medical Permit Application be denied. (VFC Document 30028389, Letter from [REDACTED] and [REDACTED] to John Hale, Office of Land Quality, IDEM, dated February 12, 2004) The Gonzales were not on the mailing list utilized by IDEM for distribution of the Notice of Decision.
5. By letter received on February 19, 2004, [REDACTED] submitted a form letter in opposition to the Midwest Medical Permit Application. (VFC Document 30028235, Letter from [REDACTED] to John Hale, Office of Land Quality, IDEM, received by IDEM on February 19, 2004) [REDACTED] was not on the mailing list utilized by IDEM for distribution of the Notice of Decision.
6. By letter dated February 19, 2004, Roy Pratt, Councilman At-Large, of the Gary Common Council, opposed the Midwest Medical Permit Application. (VFC Document 30028235, Letter from Roy Pratt, Councilman At-Large, Gary Common Council, to John Hale, Office of Land Quality, IDEM, dated February 19, 2004) Councilman Pratt was not on the mailing list utilized by IDEM for distribution of the Notice of Decision, although notice was provided to the

John Hale, Office of Land Quality, IDEM, dated March 2, 2004) Senator Smith was on the mailing list utilized by IDEM for distribution of the Notice of Decision.

14. In a letter received by IDEM on March 3, 2004, [REDACTED] requested that IDEM not allow the processing of medical waste in Gary. (VFC Document 30026047, Letter from [REDACTED] to John Hale, Office of Land Quality, IDEM, received by IDEM on March 3, 2004) [REDACTED] was on the mailing list utilized by IDEM for distribution of the Notice of Decision.

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Appendix B
The Notice of Decision

May 7, 2004

NOTICE OF DECISION

Indiana Department of Environmental Management

Please be advised that the Indiana Department of Environmental Management, Office of Land Quality, has issued a solid waste processing facility construction/operation permit for the Midwest Medical Solutions infectious waste processing facility, which is located at 1310 Michigan Street, Gary, Lake County, Indiana. This permit allows Midwest Medical Solutions, LLC, to construct and operate an infectious waste processing facility. A copy of this permit is available for review at the IDEM Northwest Regional Office located at 504 Broadway, Suite 418, Gary, Indiana, or on the IDEM website at <http://www.in.gov/idem/land/permits/notices>.

If anyone wishes to challenge this decision, IC 13-15-6-1 and IC 4-21.5-3-7 requires that they file a petition for administrative review not later than fifteen (15) days after being served with this notice. Under IC 13-15-6-7(c) you are considered to be served with this notice when you are personally served with the notice or three (3) days after the notice is deposited in the United States mail and addressed to you, whichever occurs first. Your petition describing your intent to challenge the IDEM decision must be submitted to the Office of Environmental Adjudication (OEA), 100 North Senate Avenue, Government Center North, Room 1049, Indianapolis, Indiana 46204.

Your filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing: (1) The date the document is delivered to the OEA, (2) The date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail, or (3) The date on which the document is deposited with a private carrier, as shown by the receipt issued by the carrier, if the document is sent to the OEA by private carrier. This petition must include facts demonstrating that the petitioner is the applicant, a person aggrieved by the decision, or a person entitled to review by law. In order to assist the permit staff in tracking appeals, we request that you submit a copy of your petition to John Hale, Permits Branch, Office of Land Quality, at 100 North Senate Avenue, P.O. Box 6015, Indianapolis, Indiana 46206. Identifying the permit decision, or other order for which you seek review by permit number, name of the application, location, or date of this notice will expedite review of the petition.

Additionally, IC 13-15-6-2 requires that such petition for administrative review include: (1) The name and address of the person making the request, (2) The interest of the person making the request, (3) Identification of any persons represented by the person making the request, (4) The reasons, with particularity, for the request, (5) The issues, with particularity, proposed for consideration at the hearing, and (6) The permit terms and conditions which, in the judgement of the person making the request, would be appropriate.

Pursuant to IC 4-21.5-3-5(d), the OEA will provide the petitioner or any person requesting notice with notice of prehearing conferences, preliminary hearings, hearing stays, or orders disposing of the petition for review if a written request for such notice is submitted to the OEA at the above address. If you have procedural or scheduling questions regarding your petition, you may contact OEA by dialing (800) 451-6027, press 0 and ask for extension 2-8591 or dial (317) 232-8591. Questions regarding the technical aspects of the permit decision should be directed to John Hale at (800) 451-6027, press 0 and ask for John Hale, or press 0 and ask for extension 2-8871 or dial direct at 317-232-8871.

Please bring this matter to the attention of persons you believe may have an interest in it.

Newspaper NOD

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Appendix C
The Response to Public Comments

**Indiana Department of Environmental Management
Response to Public Comments
Midwest Medical Solutions
Infectious Waste Processing Facility Application**

On October 9, 2001, Midwest Medical Solutions, LLC, (Midwest Medical) submitted to the Indiana Department of Environmental Management (IDEM) an application for a construction/operation permit for the Midwest Medical Solutions Medical Waste Processing Facility (facility). This application is a request to construct and operate a solid waste processing facility to treat both infectious and non-infectious medical waste. The proposed processing facility will be owned and operated by Midwest Medical.

IDEM received public comments concerning this application both in writing and at a public hearing held in Gary on July 11, 2002, and its attendant public comment period. Among the public comments received by IDEM was correspondence from the City of Gary Zoning Administrator indicating that the proposed facility was not properly zoned. Midwest Medical subsequently filed a lawsuit in Lake County Superior Court regarding Gary's denial of zoning for the solid waste processing facility proposed by Midwest Medical.

In order to obtain a solid waste facility processing permit, an applicant is required to submit, in part, certification verification from the zoning authority that proper zoning approvals have been obtained (329 IAC 11-9-2(a)(12)). Because Midwest Medical did not have the proper zoning from the City of Gary Zoning Administrator, IDEM denied Midwest Medical's application on September 17, 2003. Midwest Medical subsequently appealed this denial.

During the course of the litigation in Lake County Superior Court between Midwest Medical and the City of Gary, the parties resolved the status of Midwest Medical's zoning. On December 24, 2003, IDEM received certification verification from the City of Gary Zoning Administrator that Midwest Medical is properly zoned to construct an infectious waste processing facility as proposed in its application.

As a result of IDEM's receipt of the zoning certification, on January 13, 2004, Midwest Medical and IDEM entered into an agreed order resolving Midwest Medical's appeal of its permit denial. Under the terms of this agreed order, IDEM recommenced review of Midwest Medical's application.

After the first public comment period, and before the denial, additional information was submitted regarding the application, including changes regarding the good character disclosure statements required under IC 13-19-4. A second public comment period was subsequently held from January 30, 2004, to March 7, 2004, to provide opportunity for written and oral technical comments from all interested parties regarding changes and additions to the application since the first comment period. The following responses have been prepared by IDEM staff to address the concerns expressed during these comment periods.

1. **Comment:** The Midwest Medical facility is not needed, particularly in light of local hospitals like Methodist Hospital with their own autoclaves, and thus does not meet the needs requirements found at IC 13-20-1 and 329 IAC 11-9-5.

Response: IDEM reviewed the information provided concerning needs and determined that while some medical facilities treat their own infectious waste on-site, there are a significant number of medical facilities that rely on commercial disposal of their infectious waste. IDEM has made a determination that the facility meets the demonstration of need criteria found at IC 13-20-1 and 329 IAC 11-9-5.

2. **Comment:** A request was made by the Lake County Solid Waste District (District) that IDEM suspend review of the Midwest Medical application until the District made a determination regarding the need for the Midwest Medical facility, or, if that were not possible, to make it a requirement in Midwest Medical's permit, if issued, that the District's affirmative needs determination be necessary before the applicant is granted approval by IDEM.

Response: IDEM is required to process permit applications in accordance with specific timeframes in the statute and does not have the authority to suspend the review based on the subject request. IDEM also does not have the authority to incorporate permit conditions that are outside its regulatory authority and must make decisions based on the facts that are present at the time of the decision.

3. **Comment:** Who is involved in the project?

Response: The regulations require that the applicant who will be responsible for the operation and the property owner sign the application. In addition disclosures must be submitted by anyone considered a responsible party which is someone that owns 20% of the applicant. For Midwest Medical the applicant and property owner is Midwest Medical Solutions, LLC, and the responsible parties are the Jonathan A. Dyke Trust, the Stephanie M. Dyke Trust, the Russell Karlins Trust, Donald J. Russ, Jr. (trustee for the Dyke trusts), and Russell Karlins (trustee for the Karlins trust).

4. **Comment:** The permit should be denied since the parties behind Midwest Medical are the same as those involved with Medical Disposal Services, Inc., which illegally operated an infectious and medical waste transfer operation in Hammond in the 1990's.

Response: IDEM has evaluated the responsible parties for Midwest Medical and determined they were not accountable for MDS' violations under IC 13-19-4. Accordingly, the underlying basic facts of record are not grounds for denial based on good character under IC 13-19-4.

5. **Comment:** The City of Gary is an environmental justice community with enough existing contamination and waste problems. IDEM needs to take this into consideration and deny Midwest Medical's permit.

Response: IDEM considered the community's environmental justice concerns. As a result, an enhanced outreach effort was made regarding Midwest Medical's application in response to Gary's status as an environmental justice community. This outreach included both a public hearing and an evening meeting between Gary community representatives and IDEM environmental justice and permits staff. Indiana law and regulations currently do not authorize denial of a solid waste permit application based on environmental justice or existing area environmental problems. The application was evaluated to assure that the proposed facility would not have an adverse environmental impact on the local community.

6. **Comment:** Midwest Medical does not yet have required air and water permits.

Response: Unless the lack of these permits constitute violations that meet the criteria for denial of application outlined at IC 13-19-4-5, which the facts of record indicate they do not, the lack of these permits does not constitute grounds for denying Midwest Medical's solid waste processing facility permit. In addition, there are no requirements in applicable Indiana statutes and regulations requiring issuance of all other environmental permits before issuance of a solid waste facility permit.

Since the boilers at the Midwest Medical facility will only burn natural gas and have limited capacity, earlier discussions with IDEM Office of Air Quality personnel indicated an IDEM air permit was not needed. Midwest Medical has stated that it has spoken to Kelly Simons of the White River Partnership Sanitary District and was told to check back after receiving the IDEM permit and see at that time if a City of Gary Sewer use permit is needed for the process.

However, it remains the responsibility of the applicant to obtain any required permits under 329 IAC 11-11-4(3). The issuance of a solid waste facility permit does not exempt Midwest Medical from its duty to comply with any other state or local requirements. Any future record of local or state environmental violations at the facility meeting the criteria at IC 13-19-4-5 or 329 IAC 11-11-6 could lead to denial or revocation of its solid waste processing facility permit.

7. **Comment:** We don't want a waste incinerator in our community.

Response: Midwest Medical's proposed facility consists of two autoclaves that will treat infectious waste using steam and pressure. The proposed facility does not meet the definition of an incinerator as it will not be burning waste.

8. **Comment:** MMS (i.e., Midwest Medical) continues to propose using truck mounted scales and weights supplied by the generator. Truck mounted scales are very inconsistent even when calibrated quarterly. Additionally there may be significant differences between the scales at the generator locations. MMS indicated that they will use the standard operating plan (SOP) to treat the waste. Under the SOP 2.0 Infectious Waste Storage and Handling they indicate that the MMS personnel will transfer the waste into the autoclave making sure densities of the waste in each are consistent. How does MMS propose to achieve this if they are weighing the containers at the customer locations or the trucks? How do they record the weight or density of each container? How do they ensure they are running the cycles at the validated weights to ensure proper decontamination?

Response: The waste is weighed before it enters the autoclave. The permit conditions require infectious waste weights to limit the autoclave loading to weights where the efficacy has been previously demonstrated and to fulfill quarterly reporting requirements. An interlocked scale and process control feeder system is provided to prevent charging more than 2,250 pounds per cycle. An automatic data logger or equivalent device is to monitor and record the date, time, and weight of infectious waste charged to each autoclave. The waste bin weights from the facility scale are required to determine the reported waste feed rate.

9. **Comment:** In this response (i.e., Midwest Medical's May 2002 RAI response) MMS proposes that all waste, which can be autoclaved, will be within 12 hours of delivery and in all instances within 72 hours of delivery. Does this mean that those wastes which are pathological and chemotherapy wastes will be treated there if they are not off site within 72 hours? MMS commented during the public hearing that all waste would be removed off site every 12 hours. Does this account for weekends and holidays as well?

Response: In Midwest Medical's May 2002 RAI response, they state infectious waste will normally be treated within 12 hours of delivery and in all instances within 72 hours. 329 IAC 11-21-10 allows infectious waste to be stored up to seven days at the site. The pathological waste will not be treated there, but stored for up to seven days before shipment to a permitted infectious waste incinerator.

10. **Comment:** The City of Gary Sewer Use Ordinance considers this type of operation an "industrial user". Based on the ordinance MMS is required to complete an application for permit to discharge. No permit has been provided. This may identify further use restrictions based on the POTW findings in the application.

Response: It is the responsibility of the applicant to obtain the local sewer permit. Midwest Medical representatives have stated that they have spoken to Kelly Simons of the White River Partnership sanitary district and was told to check back after receiving the IDEM permit and see if a City of Gary Sewer use permit is needed for the process.

11. **Comment:** How does this (i.e., Midwest Medical's plans) protect the storm water from potential spills or leaks from spills within the vehicles during loading and unloading operations? How do they propose to clean out and disinfect the containers without potential contamination of the local water supply?

Response: The permit application provides a description of adequate emergency contingency plans including spill procedures.

The empty reusable containers will be transferred from the autoclave after the treated waste is transferred to the compactor and taken to the tub wash area for decontamination using 180 degree water and/or an EPA registered disinfectant in accordance with the manufacturer's requirements. The rinsate from the container wash operation will be discharged to the sanitary sewer.

12. **Comment:** What are the operating parameters for the autoclaves and how will they be tested to determine if they are functioning properly?

Response: The efficacy test procedure includes placing an ampoule on top of an infectious waste bag near the center of the bin, placing infectious waste bags to be autoclaved on top of the ampoule, and retrieving the ampoule for testing after autoclaving. The autoclave operating parameters require that the infectious waste will be treated at 40 psig (gauge pressure relative to atmospheric pressure) at 285° F (minimum) for a residence time of at least 25 minutes at that pressure and temperature.

13. **Comment:** How does Midwest Medical know how much waste to load into each bin based on the way they weigh their containers?

Response: The permit specifications limit the amount of infectious waste that can be loaded into the autoclave to amounts where previous tests have demonstrated efficacy.

14. **Comment:** How are the bins transferred into the autoclave? Are they conveyed or manually transferred?

Response: The bins will be manually transferred into the autoclave.

15. **Comment:** Is there a safety to ensure the autoclave cannot be opened under pressure?

Response: The permit requires that the autoclave be at atmospheric pressure when the door is opened. The effective autoclave treatment of bacteria spores and satisfying the atmospheric pressure requirement for opening the door will be demonstrated in required pre-operational tests.

16. **Comment:** How are the bins transferred out of the autoclave and transferred to the compactor?

Response: The bins of treated solid waste will be transported within the facility from the autoclaves into a solid waste compactor via a forklift or automated tipper.

17. **Comment:** How will the facility monitor for radioactive waste?

Response: The permit requires a radiation detector to detect inappropriate radioactive waste, and specifies what steps to be taken if detected.

18. **Comment:** There is opposition to out-of-state infectious waste.

Response: Federal court decisions have determined that interstate shipment of waste cannot be blocked by state law or regulations. United States Department of Transportation rules regulate the type of infectious waste containers and shipping of the infectious waste.

19. **Comment:** Infectious waste can transmit pathogens causing dangerous diseases.

Response: The infectious waste is bagged at the generating facilities, placed in required shipping containers, placed in bins, and then autoclaved without opening the bags. The proposed facility and process are designed to prevent exposure to infectious waste.

20. **Comment:** Accidents may expose citizens.

Response: Midwest Medical has provided a description of adequate emergency contingency plans, including spill procedures. As noted above, United States Department of Transportation rules regulate the type of infectious waste containers and shipping of the infectious waste. In addition, Midwest Medical has safely shipped infectious and medical waste to and from its current operation for the last several years without any known highway accidents. With the installation of the autoclaves, the waste being shipped out for disposal will be treated solid waste instead of the untreated infectious waste now being sent for disposal.

21. **Comment:** There was a concern about the amount of infectious waste.

Response: The permit application has an expected daily volume of 22 tons of infectious waste. The Bondtech autoclaves and the treatment process are designed for the expected daily volume.

22. **Comment:** The proposed location is within a mile radius of three public schools and several daycare centers.

Response: There are currently no setback requirements for solid waste processing facilities in Indiana statutes or regulations. The proposed facility has been evaluated to assure it does not pose a threat to human health or the environment.

23. **Comment:** There was a concern about exposure to ethyleneoxide gas.

Response: The applicant's infectious waste autoclave treatment process uses steam; ethylene oxide is not used.

24. **Comment:** There was a claim that Midwest Medical's current operation is illegal.

Response: Midwest Medical currently conducts direct truck-to-truck transfer of packaged infectious waste. Such direct transfer of packaged infectious waste between two vehicles, where the packaged infectious waste is not opened during the transfer, is excluded at IC 13-11-2-235 from the definition of a transfer station and thus does not need a solid waste processing facility permit. There are currently no known operational violations at this operation.

25. **Comment:** Where is the infectious waste going to be stored and processed?

Response: The infectious waste will be stored inside the existing enclosed building at the site, while some pathological waste that will be shipped off-site for processing will be stored in a refrigerated trailer by this building. The infectious waste will be placed in bins that are autoclaved in one of the two Bondtech autoclaves.

26. **Comment:** Concerns were expressed on mercury emissions.

Response: The facility must document and request at least once from each generator that each generator has a process or procedures which prevent inclusion of mercury wastes in the infectious waste to be autoclaved at the Midwest Medical facility.

27. **Comment:** Where is the danger?

Response: To remove the danger of pathogens in infectious waste, Title 410 of the Indiana State Board of Health, 410 IAC 1-3-26 (a) states all persons and facilities subject to this rule shall either effectively treat infectious waste in accordance with this rule or transport infectious waste off-site for effective treatment in accordance with this rule. (b) A treatment is effective if it reduces the pathogenic qualities of infectious waste for safe handling, is designed for the specific infectious waste involved, and is carried out in a manner consistent with the rule. Effective treatment may include: (1) incineration; (2) steam sterilization; (3) chemical disinfection; (4) thermal inactivation; (5) irradiation; or (6) discharge in a sanitary sewer or septic system that is properly installed and operating in accordance with state and local laws.

Midwest Medical's infectious waste steam autoclaving process is acceptable under the steam sterilization treatment category. Any pathological waste, antineoplastic waste or chemotherapy waste, and packaged waste identified as variant Creutzfeld-Jakob Disease (Mad Cow Disease) waste are not acceptable for processing in the autoclave and are all required by the permit to be stored in a refrigerated trailer and transferred for off-site processing.

28. **Comment:** Why locate the autoclaving facility in Gary?

Response: The regulations do not specify where facilities should be located. Such decisions are made by the applicant based on various business influences such as availability of property, proximity to waste markets, transportation routes, etc. The regulations do require that a facility be properly zoned for the proposed use.

29. **Comment:** Who will inspect the facility?

Response: IDEM inspectors will inspect the facility to determine if it is operating according to its permit requirements.

30. **Comment:** What type of protective clothing will workers wear at the facility?

Response: Midwest Medical has indicated that all employees will wear uniforms, including latex gloves and eye protection. Forklift operators will be required to wear face shields. All OSHA and State Board of Health regulations will be followed. In addition, a shower will be installed in the break room and eyewash stations will be installed in the main building.

31. **Comment:** What if Midwest Medical leaves in five years and we get stuck with a bunch of waste?

Response: The solid waste regulations require that Midwest Medical establish financial assurance to cover the cost of closure and post-closure activities for the facility. The financial assurance mechanism provides money to IDEM to properly close the facility in the event the responsible party cannot. Closure includes removal of all waste on site.

